



### General

### Guideline Title

Primary care approach to the HIV-infected patient.

### Bibliographic Source(s)

New York State Department of Health. Primary care approach to the HIV-infected patient. New York (NY): New York State Department of Health; 2011 Apr. 31 p. [7 references]

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Primary care approach to the HIV-infected patient. New York (NY): New York State Department of Health; 2007 Mar. 27 p.

## Recommendations

## Major Recommendations

The quality of evidence (I-III) and strength of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

What's New — April 2011 Update

- Section II: Comprehensive Baseline History has been updated, including the table titled "Elements of a Comprehensive General History for HIV-Infected Patient" (see below and the original guideline document)
- Select terms in the table have been hyperlinked, allowing quick reference to related guidelines from the New York State Department of Health (NYSDoH) AIDS Institute (see the original guideline document for the links)
- A column in the table has been added to identify elements of the history that require ongoing assessment

#### Introduction

Primary care clinicians should be capable of evaluating HIV-infected patients at all stages of HIV infection and should consult with a clinician who has experience with management of antiretroviral therapy (ART) according to current guidelines (see the National Guideline Clearinghouse [NGC] summary of the NYSDoH guideline Antiretroviral Therapy). (III)

Clinicians should involve patients in decisions regarding HIV treatment. (III)

Clinicians should schedule routine monitoring visits at least every 4 months for all HIV-infected patients who are clinically stable. (III)

#### Comprehensive Baseline History

#### Clinicians should:

- Obtain an HIV-related history at baseline (see table below titled "Elements of a Comprehensive General History for HIV-Infected Patient"). (AI)
- Use vocabulary that patients can understand, regardless of education level, when obtaining the history. (AIII)
- Use translator or sign language services when language barriers exist. (AIII)

Clinicians who treat HIV-infected patients should attempt to obtain previous medical records, including documentation of positive U.S. Food and Drug Administration (FDA)-approved diagnostic and confirmatory HIV tests (see the NGC summary of the NYSDoH guideline Diagnostic, Monitoring, and Resistance Laboratory Tests for HIV) (AIII).

Clinicians should educate patients with reportable illnesses in New York State about the potential for confidential follow-up from the New York State Department of Health.

Clinicians should address the importance of partner notification with HIV-infected patients and should stress the confidential nature of discussions regarding sexual history and substance use.

History	Baseline	Ongoing
General	Contact information—patient contact information, as well as contact person for emergencies or if unable to reach patient	At each visit
	Review of sources of past medical care; obtain medical records whenever possible	
	Past hospitalizations, surgeries, past and current illnesses, and recent hospitalizations	At each visit, recent and current illnesses
	Tuberculosis (TB) history	At least annually
	<ul> <li>Possible recent exposure to tuberculosis</li> <li>History of positive TST (TB skin test, commonly known as PPD), TB disease, or treatment of latent TB infection</li> </ul>	
	History of hepatitis A virus (HAV), hepatitis B virus (HBV), and hepatitis C virus (HCV), if known	
	History of chickenpox or shingles	
	Current prescription and nonprescription medications, including treatment for opioid dependence (methadone and buprenorphine); hormones; over-the-counter (OTC) agents (nonsteroidal anti-inflammatory drugs [NSAIDs], antihistamines, dietary supplements, vitamins); and other non-prescription medicines, including complementary and alternative medicines	Conduct thorough medication history at each visit
	Vaccination history	
	Reproductive history, including pregnancies, births, termination of pregnancy; current contraceptive use and contraceptive needs	At least annually
	Partner information for disclosure of HIV status	
	Transfusion or blood product history, especially before 1985	
	Complete family medical history and chronic medical conditions, particularly those that might affect the choice of antiretroviral therapy (ART) or response to therapy:	
	<ul><li>Hyperlipidemia and cardiovascular disease</li><li>Peripheral neuropathy</li></ul>	

	Diabetes and renal insufficiency  History and results of neurocognitive screening	
	History and results of cancer screening	See Table 5 in the original guideline document
	Allergies	At least annually
	Travel history/place of birth	
	Occupational history and hobbies	
	Pets/animal exposures	At least annually
HIV Staging	HIV exposure history	
	<ul><li>Date and place of the diagnosis</li><li>Route of exposure, if known</li></ul>	
	Most recent viral load and CD4 count	See Table "Routine Laboratory Assessment and Diagnostic Screening" below
	Nadir CD4 and peak viral load	
HIV Treatment History	Drug-resistance, co-receptor tropism, and human leukocyte antigen testing	See Table "Routine Laboratory Assessment and Diagnostic Screening" below
	<ul> <li>Current and previous ART regimens</li> <li>Date of initiation of ART</li> <li>Response to current and previous regimens</li> <li>Reasons for changes in ART</li> <li>Adherence to therapy</li> <li>Previous adverse ART and HIV-related drug reactions, including hypersensitivity reactions to prior therapies such as non-nucleoside reverse transcriptase inhibitors (NNRTIs), abacavir (ABC), and sulfonamides</li> </ul>	At each routine monitoring visit: Response to current regimen and adherence
	Opportunistic infections (OI) and malignancies	
	Previous adverse reactions to drugs used for OI prophylaxis	
	Providers who have been involved in the patient's HIV treatment	
	Patient's understanding of HIV disease and treatment	Ongoing assessment of health literacy
Mental Health	<ul> <li>Mental health diagnoses, especially</li> <li>Depression</li> <li>Anxiety</li> <li>Post-traumatic stress disorder</li> <li>Suicidal/violent behavior</li> <li>Severe and persistent mental illness</li> </ul>	Routine mental health screening at least annually. See Mental Health Screening Card (see the "Availability of Companion Documents" field)
	Psychotropic medications	At each visit, assess medication adherence, if applicable

Table: Flament	c of a Commencina General History for LIIV Infrated Detions		
Sable: Flement Use	s of a Corporal Seneral History for HIV-Infected Patients	Routine substance use screening at least annually.	
	<ul> <li>Street drugs—marijuana, cocaine, heroin, methamphetamine, 3,4- Methylenedioxymethamphetamine (MDMA)/ecstasy, tryptamines</li> </ul>	See Screening and Ongoing Assessment for Substance Use and	
	Illicit use of prescription drugs	Substance Use Screening Card	
	<ul><li>Alcohol</li><li>Tobacco</li></ul>	(see the "Availability of Companion	
	Tobacco	Documents" field)	
	Frequency of use and usual route of administration		
	Risk behaviors—drug/needle sharing, exchanging sex for drugs, sexual risk-taking while under the influence of drugs or alcohol	At least annually	
	History of treatment and barriers to treatment, including adherence in the setting of mental health and substance use		
Sexual	Current sexual activity	At least every 4 months	
	History of sexually transmitted infections—syphilis, herpes simplex, genital/rectal warts (human papilloma virus), chlamydia, gonorrhea, chancroid	See Table "Routine Laboratory Assessment and Diagnostic Screening" below for ongoing sexually transmitted infection (STI) assessment	
	Sexual practices—vaginal, anal, oral	At least every 4 months	
	Gender identity		
	Past and current partners	At least every 4 months	
	Risk behavior assessment, including knowledge about and use of latex or polyurethane barriers, number of partners	At least every 4 months	
	Sexual function (libido, erectile dysfunction, etc.)	At least annually	
	Use of sex-enhancing agents or testosterone replacement	At least annually	
Psychosocial	Housing status	Psychosocial assessment should b	
	Employment and insurance status	performed at least annually*	
	Educational level		
	Social support		
	Family and partner contacts		
	People patients have informed of their HIV status		
	Stability of personal relationships, as well as history of mental or physical trauma		
	(violence abuse); screen for:		
	Domestic violence screening/intimate partner violence		
	<ul><li> Elder violence</li><li> Abuse during childhood</li></ul>		
	Legal issues		
	Living will and health care proxy		
	<ul> <li>Living will and health care proxy</li> <li>Permanency planning for dependent children</li> </ul>		
	How patients are coping with their HIV status		
	Obtain names and contact information for substance use, mental health, housing and		

	Home health care	
Review of Systems	Constitutional—weight loss, malaise or fatigue, fevers, night sweats, changes in appetite, changes in sleep, adenopathy, frailty, use of ambulatory aides or wheelchair	Review of systems should be performed at least annually
	Eyes—change in vision, including blurry vision, double vision, flashes of light, or loss of vision, glasses, legally blind or blind	
	Head, ears, nose, throat—headache, dysphagia, odynophagia, hearing loss, deafness, discharge, dental pain, periodontal disease, oral herpes simplex, denture fit, mastication	
	Pulmonary—cough, dyspnea at rest or on exertion, hemoptysis	
	Cardiac—chest pain, palpitations, heart murmur	
	Abdominal—nausea, vomiting, diarrhea, constipation, rectal bleeding, hemorrhoids	
	Genitourinary:	
	<ul> <li>Vaginal or penile discharge, vaginal pain, dysuria, genital/rectal warts (human papilloma virus), classic and atypical herpes simplex virus</li> <li>Obstetrics/Gynecology (OB/GYN)—menstrual status, bleeding, infections, last</li> </ul>	
	Pap test and result  Perimenopausal or menopausal symptoms	
	Urinary symptoms (incontinence, frequency, etc.)	
	Extremities—muscle wasting, muscle weakness, muscle pain, joint swelling	
	Neurologic—cognitive changes, tingling, burning, pain, or numbness in the extremities, weakness, coordination, gait	

<sup>\*</sup>Clinicians should work with the patient's case manager to provide necessary medical guidance related to psychosocial issues that are potential barriers to treatment adherence. When case managers are unavailable, clinicians should refer their patients to social workers who can provide psychosocial services and facilitate referrals to supportive services.

### Comprehensive Physical Examination

Clinicians should perform a baseline and annual comprehensive physical examination, with particular attention to areas potentially affected by HIV (see the table below).

Table: HIV-Related Physical Examination <sup>1</sup>		
Vital signs, weight, and symptoms <sup>2</sup>	Assess at each visit	
Pain assessment	Assess at each visit	
Ophthalmologic	Perform or refer for a funduscopic examination <sup>3</sup>	
Head, ears, nose, throat	Sinus infection, odynophagia, dysphagia, hearing loss	
Oral	Oral candidiasis (thrush), hairy leukoplakia (examine lateral borders of tongue), Kaposi's sarcoma, gingival disease, aphthous ulcers	
Dermatologic	Rash, pruritus, psoriasis, molluscum contagiosum, seborrheic dermatitis, maceration of the gluteal cleft, Kaposi's sarcoma, onychomycosis, diffuse folliculitis with pruritus, melanoma	
Lymph nodes <sup>4</sup>	Particular attention to axillary, posterior cervical chain, supraclavicular, submental, epitrochlea, femoral	
Endocrinologic	Abnormal subcutaneous fat redistribution	

Fable: Hary-Related Ph	ysical Francis to wheezes, rhonchi, rales, or dullness
Cardiac examination	Heart rhythm, heart murmur, click or rub
Abdominal	Hepatosplenomegaly, multiple lipomata in the subcutaneous fat, increased visceral fat
Genital	<ul> <li>Genitourinary: vaginal or penile discharge, vaginal pain, ulcerative genital disease</li> <li>Obstetric/gynecologic: careful pelvic examination</li> </ul>
Rectal	<ul> <li>Visible anal lesions or evidence of skin abnormality around the anus</li> <li>Digital rectal exam</li> <li>Symptoms: itching, diarrhea, pain</li> </ul>
Musculoskeletal	<ul> <li>Extremities, muscle wasting</li> <li>Peripheral pulses</li> <li>Evidence of peripheral vascular disease</li> </ul>
Neuropsychological	<ul> <li>Reflex, sensory, motor, and cerebellar function</li> <li>Signs of multifocal motor and sensory nerve abnormalities especially peripheral neuropathy</li> <li>Cranial nerves</li> <li>Cognitive status examination</li> <li>Mental health and substance use assessment</li> </ul>

<sup>&</sup>lt;sup>1</sup>Except where indicated, each element should be performed at baseline and at least annually

Vital Signs, Symptoms, and General Appearance

Clinicians should assess vital signs and weight at each visit. (III)

Clinicians should inquire about new symptoms at each visit. (III)

Clinicians should note changes in general appearance, body habitus, and physical well-being. (III)

#### Pain Assessment

Clinicians should ask HIV-infected patients about pain at each visit, as well as document any complaints of pain, attempt to identify underlying causes, and respond with efforts to alleviate it. (III)

Clinicians should not deny treatment of pain because of a patient's history of addiction. (III)

Clinicians should assess patients with chronic pain for fatigue and mental health disorders and include referral to a pain-management specialist as a treatment option. (III)

Ophthalmologic Assessment and Referral

Patients with CD4 counts <50 cells/mm<sup>3</sup> should be examined by an ophthalmologist at baseline and every 6 months. (III)

Patients with visual disturbances or unremitting ocular symptoms, regardless of CD4 cell count, should be evaluated by an ophthalmologist. (III)

<sup>&</sup>lt;sup>2</sup>Assessment of symptoms may require direct questioning because patients may not consider their symptoms important until after the symptoms have already caused significant morbidity.

<sup>&</sup>lt;sup>3</sup>Patients with CD4 counts <50 cells/mm<sup>3</sup> should be examined by an ophthalmologist at baseline and every 6 months.

<sup>&</sup>lt;sup>4</sup>Significant abnormalities may present as clusters of large nodes, asymmetry, tenderness, or sudden increases in size or firmness of nodes.

#### Oral Examination

Clinicians should ascertain whether their patients have a regular oral health provider and should refer all HIV-infected patients for annual hygiene and intraoral examinations, including dental caries and soft-tissue examinations. (III)

#### Genital and Rectal Examination

Clinicians should examine all HIV-infected patients for ulcerative lesions. (III)

Clinicians should perform a gynecologic examination in all HIV-infected women or refer them to a gynecologist at baseline and at least annually. (II)

At baseline and as part of the annual physical examination for all HIV-infected adults, regardless of age, clinicians should (III):

- Inquire about rectal symptoms, such as itching, bleeding, diarrhea, or pain
- Perform a visual inspection of the perianal region
- Perform a digital rectal examination

Clinicians should refer women with cervical high grade squamous intraepithelial lesion (HSIL) and any patient with abnormal anal physical findings, such as warts, hypopigmented or hyperpigmented plaques/lesions, lesions that bleed, or any other lesions of uncertain etiology, for high-resolution anoscopy and/or examination with biopsy of abnormal tissue.

#### Neuropsychological Examination

#### Neurologic Examination

Clinicians should examine for sensory and motor abnormalities, especially peripheral neuropathy, cerebellar function, and cognitive impairment.

Clinicians should refer patients with more complex suspected or proven peripheral neuropathy syndromes to a neurologist to assist with the diagnosis and management.

Mental Health and Substance Use Assessment

Clinicians should perform a mental health assessment at baseline and at least annually. The assessment should include the following components (I):

- Depression, anxiety, post-traumatic stress disorder, suicidal/violent ideation, and substance use
- Sleep habits and appetite assessment
- Psychiatric history, including psychotropic medications
- · Psychosocial assessment, including domestic violence and housing status

Clinicians should refer patients to appropriate mental health and substance use treatment providers when indicated. (II)

Clinicians should incorporate selected brief screening instruments into the assessment process. The chosen screening instruments should be tailored for optimal use at initial, annual, and interim visits and adjusted for the patient's mental health or substance use history. (III)

#### Laboratory Assessment and Diagnostic Testing

Clinicians should order appropriate laboratory assessments and screening tests for management of HIV-infected patients (see the table below). (III)

Table: Routine Laboratory Assessment and Diagnostic Screening		
Assessment	Diagnostic Screen	Frequency
Immunologic assessment	CD4 lymphocyte count and percentage; to produce reliable results, the same testing laboratory should be used	Baseline and at least every 4 months
Virologic assessment	<ul> <li>Quantitative HIV ribonucleic acid (RNA) testing for viral load assessment; the same testing laboratory should be used<sup>1</sup></li> <li>Resistance testing</li> </ul>	Baseline and at least every 4 months  1. Baseline regardless whether ART is being initiated (genotypic testing)  and

Table: Routine	Laboratory Assessment and Diagnostic Screening	Prior to initiating treatment in ART-naive patients (genotypic testing)     and     When patients experience virologic
		failure or incomplete viral suppression while receiving ART (genotypic and/or phenotypic testing <sup>2</sup> )
Tuberculosis evaluation	<ul> <li>TST<sup>3</sup> or other FDA-approved test for patients with no previous history of TB or no previous positive TST</li> <li>Chest x-ray for patients known to have a history of TB or known to be TST positive</li> </ul>	Baseline and annually
Screening for sexually transmitted infections <sup>4</sup>	Rapid plasma reagin (RPR) or Venereal Disease Research Laboratory (VDRL) for syphilis with verification of positive test by confirmatory fluorescent treponemal antibody absorbance (FTA-Abs) or <i>Treponema pallidum</i> particle agglutination (TP-PA)	Baseline and at least annually; every 3 months for patients with continued high-risk behavior
	<ul> <li>Gonorrhea and chlamydia<sup>5</sup></li> <li>Sexually active women &lt;25 years of age</li> <li>Women ≥25 years of age with risk factors<sup>6</sup></li> <li>All HIV-infected men with ongoing high-risk behavior</li> </ul>	Baseline and at least annually
Cytologic Screening	Cervical Pap tests	Baseline, 6 months after baseline, then annually, as long as results are normal <sup>7</sup>
	Anal Pap tests  • For men who have sex with men  • Any patient with a history of anogenital condylomas  • Women with abnormal cervical/vulvar histology	Baseline and annually
Hematologic assessment	Complete blood count, including differential	Baseline and at least every 4 months
Renal	Urinalysis	Baseline and at least annually
assessment	Serum creatinine <sup>8</sup> , blood urea nitrogen (BUN), total protein, albumin	Baseline and at least every 4 months
Metabolic assessment	<ul> <li>Fasting blood glucose</li> <li>Fasting lipid profile, including cholesterol</li> </ul>	<ul> <li>For patients receiving ART: before initiating ART, 3 to 6 months after initiating, and annually thereafter</li> <li>For patients not receiving ART: at baseline and annually</li> </ul>
Hepatic assessment	<ul><li>Hepatitis A serology</li><li>Hepatitis B serology</li></ul>	Baseline
	Hepatitis C serology <sup>9</sup>	Baseline; baseline and annually for patients at risk 10

Table: Routine	Serum liver enzymes Laboratory Assessment and Diagnostic Screening	Baseline and at least every 4 months for patients receiving ART
Additional tests <sup>11</sup>	<ul> <li>Amylase and lipase testing</li> <li>Toxoplasma gondii antibody screening</li> <li>Varicella antibody screening for adults without a history of chickenpox</li> </ul>	Baseline

 $^{1}$ The initial test performed in an ART-naive individual should be an assay that can document a potentially high viral load level. All patients with a viral load <400 copies/mL should be retested with an assay that can detect ≤50 copies/mL; the same testing laboratory and the same assay should be used thereafter.

<sup>2</sup>For additional information regarding genotypic and phenotypic testing, refer to HIV Resistance Assay in the NGC summary of the NYSDoH guideline Antiretroviral Therapy.

<sup>3</sup>Tuberculin skin test, commonly known as purified protein derivative (PPD).

<sup>4</sup>Patients who continue to engage in unsafe sexual practices are at increased risk for other STIs. Patients with any other STIs, whether ulcerative or not, are at higher risk for HIV transmission. Recent increases in STIs among men who have sex with men warrant screening of asymptomatic sexually active patients (see the NYSDoH guidelines for Management of STIs in HIV-Infected Patients).

<sup>5</sup>All sites of possible exposure are screened.

<sup>6</sup>Risk factors for women ≥25 years of age include one of the following: recent STI, having multiple sexual partners, having had a new sexual partner, or having a sexual partner with symptoms of an STI.

<sup>7</sup>Colposcopy should be performed for all HIV-infected women with abnormal Pap tests. Follow-up would then vary on a case-by-case basis. Abnormal Pap tests should be repeated every 3 to 6 months thereafter until there have been two successive normal cervical Pap tests. Women with cervical high-grade squamous intraepithelial lesion [HSIL] should be referred for high-resolution anoscopy and/or examination with biopsy of abnormal tissue.

<sup>8</sup>Routine calculation of estimated glomerular filtration rate is also recommended.

<sup>9</sup>A qualitative hepatitis C virus (HCV) RNA polymerase chain reaction (PCR) should be obtained when no hepatitis antibodies are detectable in a patient with elevated serum liver enzymes and risk factors for HCV.

<sup>10</sup>HIV-infected patients who are seronegative for HCV but have continued high-risk behaviors should be screened at least annually for HCV. Individuals at high risk include injection drug users, men who have sex with men without barrier protection, or anyone with multiple sexual partners (see the NYSDoH guideline Hepatitis C Virus).

<sup>11</sup>Depending on the patient's history, these additional baseline tests may be needed.

Immunologic Assessment

The CD4 lymphocyte profile should include both the absolute count and percentage. (I)

Virologic Assessment

Clinicians should use an assay, with a high upper limit of detection (e.g.,  $\geq$ 750,000 copies/mL) for initial measurement of HIV viral load in ART-naive patients. All patients with a viral load of <400 copies/mL after the initial test should be monitored with an assay that can detect  $\leq$ 50 copies/mL. (III)

Clinicians should obtain viral load before vaccinations and not during intercurrent illness because these situations may lead to a transient elevation in viral load. (III)

Clinicians should perform resistance testing under the following circumstances:

- At baseline, regardless of whether ART is being initiated (genotypic testing)
- In ART-naive patients before initiation of ART (genotypic testing)

In patients experiencing treatment failure or incomplete viral suppression while receiving ART (genotypic and/or phenotypic testing)

Clinicians should seek expert consultation for interpretation of genotypes. (III)

Tuberculosis Evaluation

Clinicians should obtain a TST (tuberculin skin test, commonly known as PPD) or other FDA-approved test for diagnosis of latent tuberculosis infection, unless the patient has previously tested positive or has had previously documented TB. (I)

After active tuberculosis has been excluded clinicians should prescribe TB prophylaxis when a TST results in induration of  $\geq$ 5 mm or when another FDA-approved test indicates the presence of latent TB infection. (I)

Laboratory Screening for Sexually Transmitted Infections

Clinicians should screen HIV-infected patients for syphilis by obtaining a non-treponemal test (RPR or VDRL) with verification of reactive test by confirmatory fluorescent treponemal antibody absorbance (FTA-Abs) or *Treponema pallidum* particle agglutination (TP-PA) tests at baseline and at least annually. Patients with continued high-risk behavior should be screened for syphilis every 3 months.

Clinicians should screen sexually active HIV-infected women under the age of 25 for gonorrhea and chlamydia at baseline and at least annually. Clinicians should screen all sites of possible exposure, including the cervix, rectum, and pharynx. Culture or nucleic acid amplification tests (NAT) should be used to screen for gonorrhea. Immunofluorescence or deoxyribonucleic acid (DNA) amplification should be used for chlamydia.

Clinicians should screen women 25 years of age or older for gonorrhea and chlamydia at baseline and at least annually if they have or have had a recent sexually transmitted infection, have multiple sexual partners, have had a new sexual partner, or have a sexual partner with symptoms of an STI.

Clinicians should screen all HIV-infected men with ongoing high-risk sexual behaviors for gonorrhea and chlamydia at baseline and at least annually. Clinicians should screen all sites of possible exposure, including the urethra, rectum, and pharynx.

Cytologic Screening

Cervical Pap Tests

Clinicians should obtain cervical Pap tests for all HIV-infected women at baseline, 6 months after baseline, and then repeat annually, as long as results are normal.

Colposcopy should be performed for women with abnormal Pap tests. Follow-up would then vary on a case-by-case basis.

Clinicians should repeat abnormal Pap tests every 3 to 6 months thereafter until there have been two successive normal cervical Pap tests. Women with cervical HSIL also should be referred for high-resolution anoscopy and/or examination with biopsy of abnormal tissue.

Clinicians should obtain at least an annual Pap test in HIV-infected women who have undergone either a supracervical or total hysterectomy.

Anal Pap Tests

Clinicians should obtain anal Pap tests at baseline and annually in the following HIV-infected populations:

- Men who have sex with men
- Any patient with a history of anogenital condylomas
- Women with abnormal cervical/vulvar histology

Clinicians should refer patients with abnormal anal cytology for high-resolution anoscopy and/or examination with biopsy of abnormal tissue. (III)

#### Health Promotion and Behavioral Health Counseling

Clinicians should provide routine HIV risk-reduction counseling and behavioral health counseling for HIV-infected patients. (I) (See Table 4 in the original guideline document.)

Safer Sex Education

Clinicians should discuss safer sexual practices with HIV-infected patients on a routine and ongoing basis. (I)

Clinicians should routinely discuss with patients the importance of disclosure to partners. Patients should be educated about the options for

voluntary partner notification. These discussions should be clearly documented. Information about HIV reporting and partner notification in New York State is available at www.health.state.ny.us . (I)

Clinicians should emphasize that transmission of HIV may occur during unprotected sex, even when patients have undetectable HIV plasma viral loads. (I)

Clinicians should recommend the correct and consistent use of latex or, when latex allergies exist, polyurethane male condoms and should discuss the option of using polyurethane female condoms. (I)

Clinicians should instruct patients in the proper use of condoms, dental dams, and other barriers to reduce the risk of HIV transmission. (I)

Clinicians should educate their patients to avoid using condoms and creams containing nonoxynol-9. (I)

Substance Use Counseling

When current alcohol or other substance use is identified, clinicians should discuss the possible effects of such use on the patient's general health and HIV medications, as well as options for treatment if indicated. These discussions should be properly documented in the patient's chart. (I)

Clinicians should evaluate for possible interactions among illicit drugs and prescription drugs. (I)

Clinicians should issue prescriptions for new needles and syringes to patients who inject drugs.

Clinicians should discuss with patients other options for accessing new needles and syringes, including use of the Expanded Syringe Access Demonstration Program and Syringe Exchange Programs, New York State's two syringe access initiatives. (I)

Clinicians should collaborate with social work staff and other mental health providers, when available, to determine which treatment programs or substance use services best meet the patient's needs. (I)

Tobacco Use Assessment and Counseling

Clinicians should assess smoking status and should encourage those who smoke to stop. (I) Pharmacotherapy and referrals to smoking cessation programs should be provided if the patient is interested.

Reproductive Counseling

Clinicians should discuss family planning with patients, including risks to the mother and fetus during pregnancy.

Domestic Violence

Clinicians or a member of the healthcare team should screen all male and female HIV-infected patients for current and lifetime domestic violence at baseline and annually. (I)

Prior to screening patients for domestic violence, clinicians should discuss confidentiality and exceptions to confidentiality, including instances of suspected child abuse and maltreatment and intent to harm self or others.

Domestic violence screening should be performed only when the patient is alone.

Psychosocial Assessment

The clinician or a member of the healthcare team should perform a psychosocial assessment of HIV-infected patients including housing status, at baseline and at least annually. (I) (Refer to Table 4 in the original guideline document.)

The clinician should work with the patient's case manager to provide necessary medical guidance related to psychosocial issues that are potential barriers to treatment adherence. (I)

Preventive Medicine

Standard Health Maintenance

Clinicians should discuss general preventive health care and health maintenance with all HIV-infected patients routinely and, at a minimum, annually. (I)

Clinicians should perform standardized age—and sex—appropriate health-maintenance interventions, such as cancer screening, in HIV-infected patients according to the same guidelines used for non-HIV-infected patients. (I) (see Table 5 in the original guideline document.)

Clinicians should instruct patients on how to perform breast and testicular self-examinations. (III)

Opportunistic Infection Prophylaxis

Clinicians should initiate prophylaxis for specific opportunistic infections as indicated in Table 6 of the original guideline document and discontinue as indicated in Table 7 of the original guideline document. (I)

### **Immunizations**

Vaccine	Indications	Schedule
Tetanus, diphtheria, and pertussis (Tdap), and tetanus-diphtheria (Td)	For patients who have not received the primary series or for whom vaccine status is unknown	<ul> <li>Administer a one-time dose of Tdap, followed by a dose of Td at 1 month and a second dose of Td 6 to 12 months later</li> <li>Administer 1 dose of Td booster every 10 years</li> </ul>
	For patients who have already received the primary series that did not include Tdap	<ul> <li>Administer one-time dose of Tdap instead of Td booster if the last dose of Td was received ≥10 years ago</li> <li>Intervals shorter than 10 years since the last Td may be used for booster protection against pertussis</li> <li>After one-time dose of Tdap, administer 1 dose of Td booster every 10 years</li> </ul>
Influenza	For all patients	Administer 1 annual dose. Do not use FluMist because it contains live virus.
Pneumococcal polysaccharide	For all patients	Administer 1 dose followed by one revaccination after 5 to 6 years (or more) have elapsed since initial vaccination
Hepatitis A	All HIV-infected patients who are negative for HAV immunoglobulin G (IgG)	Administer 2 doses (0 and 6 to 12 months)
Hepatitis B	For patients without serologic evidence of prior HBV infection or who have not previously received the complete series of HBV vaccination	Strongly encourage the vaccine series—3 doses (0, 1 to 2, and 6 months)
Measles, mumps, rubella (MMR)	For all asymptomatic HIV-infected patients who do not have evidence of severe immunosuppression and who are seronegative for antibody to MMR	Administer 1 dose
	For patients with severe immunosuppression (<200 cells/mm³)	Do not administer vaccine
Human papillomavirus (HPV)	For women between the ages of 9 and 26 years	Administer 3 doses (at 0, 2, and 6 months)
Varicella	For persons who are susceptible	Consider administering 2 doses (at 0 and 4 to 8 weeks)

Refer to the original guideline document for additional information on immunizations.

#### Coordination of Care

As part of the initial visit, the clinician or other member of the healthcare team should educate new patients on the following items (III):

- How to access emergency services (provide a phone number for 24-hour services)
- Whom to contact to schedule appointments
- · How to obtain laboratory and radiology results, medical records, and other reports

After receiving patient consent, clinicians should share information with other agencies from which their patients are receiving services. (III)

Case management should be used to enhance coordination of care provided by agencies such as home care, nutrition services, and nursing services and to prevent duplication of services. (III)

Clinicians should regularly involve case managers in case conferences to discuss psychosocial issues that may affect a patient's ability to adhere to care. (III)

#### Appropriate Use of Acute Care Services

Outpatient clinicians who do not provide inpatient care should have a network of practitioners with whom they can communicate easily should their patients require hospitalization. (III)

Inpatient clinicians should ensure that the details of hospitalization, including the discharge medications and plans, are sent in a timely fashion to the outpatient clinicians. (III)

#### Appropriate Use of Chronic Care Services

#### Home Health Care

Home health nurses should be provided with a copy of the patient's medication list and information regarding current medical conditions and mental health or substance use disorders. (III)

#### End-of-Life Care

Clinicians should encourage patients to prepare an advanced directive and designate a health care proxy and should review these arrangements at least annually.

As HIV disease progresses, clinicians should discuss patients' feelings about end-of-life care before they are unable to make decisions. Any medical decisions that are made should be in conjunction with the patient, or, if the patient is unable to decide for neurologic reasons, with the patient's health care proxy. (III)

Clinicians should be familiar with hospice services available in their area and should make referrals to them early enough for the patient to receive the full benefit of their support. (III) Clinicians should work in conjunction with hospice staff to establish which medical interventions may still be appropriate as quality of life evolves or changes. (III)

### **Definitions**:

Quality of Evidence for Recommendation

- I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
- II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
- III. Expert opinion

#### Strength of Recommendation

- A. Strong recommendation for the statement
- B. Moderate recommendation for the statement
- C. Optional recommendation

# Clinical Algorithm(s)

An algorithm is provided in the original guideline document for screening and managing suicidal or violent patients is available in the mental health

# Scope

Counseling

## Disease/Condition(s)

- Human immunodeficiency virus (HIV) infection
- General physical, psychological, and reproductive health

Guidel	line (	Category
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Evaluation	
Management	
Prevention	
Screening	

# Clinical Specialty

Allergy and Immunology

Family Practice

Infectious Diseases

Internal Medicine

Nursing

Obstetrics and Gynecology

Preventive Medicine

### **Intended Users**

Advanced Practice Nurses

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

# Guideline Objective(s)

To develop guidelines for evaluation and management of human immunodeficiency virus (HIV)-infected patients in primary care

### **Target Population**

Human immunodeficiency virus (HIV)-infected patients in primary care

### **Interventions and Practices Considered**

#### Evaluation/Assessment

- 1. General history including:
  - Past hospitalizations, past and current illnesses
  - · Current prescription and non-prescription medicines
  - Vaccination history
  - Reproductive history
  - Partner information for disclosure of human immunodeficiency virus (HIV) status
  - Occupational history
  - Allergies HIV treatment and staging including
  - HIV exposure history
  - Most recent viral load and CD4 count
  - Current and previous antiretroviral (ARV) regimens
  - Previous adverse ARV drug reactions
  - Opportunistic infections
- 2. Mental health and substance use history
- 3. Sexual history
- 4. Psychosocial history
- 5. Review of systems
- 6. Comprehensive physical examination including:
  - Vital signs and pain assessment
  - Ophthalmologic assessment and referral
  - Head, ears, nose, and throat examination
  - Oral examination
  - Dermatologic examination
  - Lymph node examination
  - Endocrinologic examination
  - Pulmonary and cardiac examination
  - Abdominal examination
  - Genital examination
  - Rectal examination
  - Musculoskeletal examination
  - Neuropsychological examination
- 7. Laboratory assessment and diagnostic testing including:
  - Immunologic assessment
  - Virologic assessment
  - Tuberculosis evaluation
  - · Screening for sexually transmitted infections
  - Cytologic screening
  - Hematologic assessment
  - Renal and hepatic assessment
  - Metabolic assessment

#### Management/Counseling

- 1. Behavioral health counseling and health promotion including:
  - Safer sex education
  - Substance use assessment and counseling
  - Smoking cessation education

- Reproductive counseling
- Domestic violence screening
- Psychosocial assessment
- Diet and exercise counseling
- 2. Coordination of care using case management
- 3. Appropriate use of acute and chronic care services

#### Prevention

- 1. Standard health maintenance interventions, such as mammogram, prostate specific antigen (PSA), colorectal cancer screen
- 2. Opportunistic infection prophylaxis (trimethoprim/sulfamethoxazole, azithromycin, clarithromycin)
- 3. Immunizations

# Major Outcomes Considered

Not stated

# Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

# Description of Methods Used to Collect/Select the Evidence

Not stated

### Number of Source Documents

Not stated

# Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

# Rating Scheme for the Strength of the Evidence

Quality of Evidence for Recommendation

- I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
- II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
- III. Expert opinion

# Methods Used to Analyze the Evidence

## Description of the Methods Used to Analyze the Evidence

Not stated

### Methods Used to Formulate the Recommendations

**Expert Consensus** 

### Description of Methods Used to Formulate the Recommendations

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with HIV infection. Committees\* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees\* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

#### \*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection
- Committee for the Care of Substance Users with HIV Infection
- Physicians' Prevention Advisory Committee
- Pharmacy Advisory Committee

## Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

- A. Strong recommendation for the statement
- B. Moderate recommendation for the statement
- C. Optional recommendation

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

### Method of Guideline Validation

External Peer Review

# Description of Method of Guideline Validation

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

# **Evidence Supporting the Recommendations**

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Appropriate evaluation and management of human immunodeficiency virus (HIV)-infected patients in primary care

### Potential Harms

Not stated

# Qualifying Statements

## **Qualifying Statements**

When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.

# Implementation of the Guideline

# Description of Implementation Strategy

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

#### Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDoH) Distribution Center for providers who lack internet access.

#### Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio

#### conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

### Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

End of Life Care

Getting Better

Living with Illness

Staying Healthy

### **IOM Domain**

Effectiveness

Patient-centeredness

# Identifying Information and Availability

# Bibliographic Source(s)

New York State Department of Health. Primary care approach to the HIV-infected patient. New York (NY): New York State Department of Health; 2011 Apr. 31 p. [7 references]

# Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2004 (revised 2011 Apr)

## Guideline Developer(s)

New York State Department of Health - State/Local Government Agency [U.S.]

## Source(s) of Funding

New York State Department of Health

### Guideline Committee

Medical Care Criteria Committee

## Composition of Group That Authored the Guideline

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### Financial Disclosures/Conflicts of Interest

Not stated

### **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Primary care approach to the HIV-infected patient. New York (NY): New York State Department of Health; 2007 Mar. 27 p.

Guideline Availability
Electronic copies: Available from the New York State Department of Health AIDS Institute Web site
Availability of Companion Documents
The following are available:
<ul> <li>Mental health screening: a quick reference guide for HIV primary care clinicians. New York (NY): New York State Department of Health; 2006 Feb. 8 p. Electronic copies: Available from the New York State Department of Health AIDS Institute Web site</li> <li>Substance use screening: a quick reference guide for HIV primary care clinicians. New York (NY): New York State Department of Health; 2009 Feb. 8 p. Available from the New York State Department of Health AIDS Institute Web site</li> </ul>
Patient Resources
None available
NGC Status
This NGC summary was completed by ECRI on January 17, 2005. This NGC summary was updated by ECRI Institute on September 18, 2007. This NGC summary was updated by ECRI Institute on October 27, 2011.

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